Complete Summary

GUIDELINE TITLE

2006 United Kingdom national guideline on the sexual health of people with HIV: sexually transmitted infections.

BIBLIOGRAPHIC SOURCE(S)

Nandwani R. 2006 United Kingdom national guideline on the sexual health of people with HIV: sexually transmitted infections. London (UK): British Association for Sexual Health and HIV; 2006 Apr. 29 p. [108 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Medical Society for the Study of Venereal Diseases (MSSVD). Clinical standards for the screening and management of acquired syphilis in HIV-positive adults. London (UK): Medical Society for the Study of Venereal Diseases (MSSVD); 2002 Feb 21. 9 p.

COMPLETE SUMMARY CONTENT

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EVIDENCE SUPPORTING THE RECOMMENDATIONS

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus type 1 (HIV) infection
- Other sexually transmitted infections, including:
 - Acquired syphilis
 - Genital herpes
 - Genital human papilloma virus (HPV)

GUIDELINE CATEGORY

Evaluation Management Screening Treatment

CLINICAL SPECIALTY

Allergy and Immunology Family Practice Infectious Diseases Internal Medicine Obstetrics and Gynecology Preventive Medicine Urology

INTENDED USERS

Health Care Providers Nurses Physicians Public Health Departments

GUIDELINE OBJECTIVE(S)

- To support people with human immunodeficiency virus (HIV) to enjoy good sexual health for their own personal well-being
- To help clinicians to provide treatment and care for people with HIV and to prevent onward transmission of the virus and sexual infections

TARGET POPULATION

Human immunodeficiency virus (HIV)-positive adults in the United Kingdom

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Screening

- 1. Sexual health assessment including sexual history taking and sexual health screening (e.g., annual cytology in women)
- 2. Incorporation of syphilis serology test into the routine human immunodeficiency virus (HIV) blood test

Management/Treatment

- 1. Establishment of local care pathways for diagnosis, treatment, and partner work
- 2. Treatment/management of primary or secondary syphilis
 - Intramuscular benzathine penicillin G
 - Adequate follow-up to detect relapses

Note: Ceftriaxone, erythromycin, and azithromycin have been considered but not recommended for treatment of syphilis

- 3. Treatment/management of genital herpes
 - First episode: aciclovir; alternative regimen: valaciclovir or famciclovir; in severe cases: intravenous aciclovir
 - Episodic herpes therapy: aciclovir, famciclovir, and valaciclovir
 - Intermittent cessation of suppressive antiviral therapy
 - Drug resistant herpes: Topical 1% foscarnet cream or 1% cidofovir gel; topical trifluorothymidine alone or in combination with interferonalpha; intravenous foscarnet or intravenous cidofovir
- 4. Treatment/management of genital human papilloma virus (HPV)
 - Treatment of low-grade cervical intraepithelial neoplasia
 - Proctoscopy and biopsy of ano-genital warts
 - Imiquimod 5% cream
 - Surgical methods of wart removal (diathermy, scissor excision, laser ablation)
- 5. Partner notification

MAJOR OUTCOMES CONSIDERED

- Rate of sexually transmitted infections in human immunodeficiency virus (HIV)-infected individuals
- Rate of treatment failure including incidence of clinical or serological relapse
- Effectiveness of drug treatments for sexually transmitted infections
- Rate of drug resistant strains
- Risk of HIV transmission following an exposure from a known person with HIV

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The process of guideline development was commenced in 2003 by commissioning and reviewing seven key supporting papers from the human immunodeficiency virus (HIV) community, relevant British Association for Sexual Health and HIV (BASHH) special interest groups, and the Faculty of Family Planning. Contributions were also supported by Cochrane search using multiple appropriate Medical Subject Heading (MeSH) terms, searching both MEDLINE and Web of Science, reviewing existing guidelines, conference abstracts and consulting with relevant communities, professional societies, and individuals.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence:

Ιa

• Evidence obtained from meta-analysis of randomised controlled trials

Ιb

• Evidence obtained from at least one randomised controlled trial

Пa

 Evidence obtained from at least one well designed controlled study without randomisation

Hb

 Evidence obtained from at least one other type of well designed quasiexperimental study

 $\Pi\Pi$

• Evidence obtained from well designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies

١V

• Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guideline has been produced by senior United Kingdom medical specialists from relevant disciplines with the input of human immunodeficiency virus (HIV) community organisations and people with HIV (PWHIV) from the outset. It takes on board concerns expressed from community groups that the sexual health needs of PWHIV have not been previously addressed in an appropriate manner. Successive drafts have been reviewed by HIV community organisations and individuals, and key professional organisations including members of British Association for Sexual Health and HIV (BASHH) and the British HIV Association (BHIVA).

This guideline was produced by reaching agreement after assessing the evidence by four key stakeholders prior to presentation to the Clinical Effectiveness Group (CEG) for wider dissemination. This process took place through extensive redrafting 2003-2006 and remains ongoing.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations:

A (Evidence Levels Ia, Ib)

 Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation

B (Evidence Levels IIa, IIb, III)

• Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation

C (Evidence Level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities
- Indicates absence of directly applicable studies of good quality

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft version of this guideline was put out to public consultation at the British Association for Sexual Health and Human Immunodeficiency Virus [HIV] (BASHH) website from November 2005 to February 2006 and was also circulated to key professional and non-statutory stakeholders. Comments received from a range of sources have been incorporated into this final document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (I-IV) and grades of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

Sexual Risk Assessment and Screening

All human immunodeficiency virus (HIV) service providers should be able to provide ready access to staff trained in taking a sexual history and who can make an appropriate sexual health assessment (Evidence level III, Grade B recommendation).

Frequency of Syphilis Serology Tests, Sexual History Taking, and Sexual Health Screening

A sexual health assessment including a sexual history should be documented at first presentation and at 6 monthly intervals for all HIV-positive people receiving long-term care. If appropriate, a full sexual health screen (including annual cytology in women) should be offered (regardless of reported history) and the outcome documented in the HIV case notes (Evidence level IIb, Grade B recommendation).

Syphilis serology should be incorporated into the routine HIV blood set and checked at 3 monthly clinic visits to detect asymptomatic cases (Evidence level IIb, Grade B recommendation).

Sexual Health Care Pathways

There should be documented local care pathways for diagnosis, treatment, and partner work for sexually transmitted infections in people with HIV which can be actively communicated to all members of clinic staff and to HIV-positive people (Evidence level IIb, Grade B recommendation).

The majority of sexually transmitted infections (STIs) in people with HIV including gonorrhoea and Chlamydial infection can be managed the same as in people without HIV (Evidence level IIb, Grade B recommendation). STIs should be considered in the differential diagnosis of presentations such as skin rash or proctitis in HIV-positive people.

Management of Syphilis in People with HIV

Primary or secondary syphilis can be treated with 2 doses of intramuscular Benzathine Penicillin G one week apart in HIV-positive people who are not profoundly immunosuppressed and in whom adequate follow-up can be maintained to detect relapses. (Evidence level Ib, Grade A recommendation).

Management of Genital Herpes in People with HIV

First Episode of Genital Herpes

First episode genital herpes in HIV-positive people should be treated with aciclovir 400 mg five times daily for 7 to 10 days. Alternative oral regimens include valaciclovir 1 gram twice daily for 10 days or famciclovir 250-750 mg x3/day for 10 days (Evidence level IIb, B). In severe cases, initiating therapy with aciclovir 5-10 mg/kg body weight intravenously (IV) every 8 hours may be necessary (Evidence level IV, Grade C recommendation).

Episodic Herpes Therapy

Aciclovir, famciclovir, and valaciclovir can all be used as episodic herpes therapy in people with HIV (PWHIV) (Evidence level Ib, Grade A recommendation). In controlled trials in herpes simplex virus (HSV) and HIV co-infected persons, famciclovir 500 mg twice daily for 7 days was as effective as aciclovir 400 mg five times daily for 7 days (Romanowski et al., 2000) (Evidence level Ib, Grade A recommendation).

Valaciclovir 1 g twice daily for 5 days was no less effective than aciclovir 200 mg five times daily for 5 days (Schacker, 1999) (Evidence level Ib, Grade A recommendation).

The US Centers for Disease Control and Prevention ("Sexually transmitted diseases," 2002) recommend the following drug regimens for episodic herpes (Evidence level IV, Grade C recommendation):

- Aciclovir 400 mg orally three times daily for 5 to 10 days
- Aciclovir 200 mg five times daily for 5 to 10 days
- Famciclovir 500 mg twice daily for 5 to 10 days
- Valaciclovir 1 g twice daily for 5 to 10 days

There is no clear evidence of superiority for any of the above regimens for episodic herpes.

Suppressive Herpes Therapy

It is recommended that intermittent cessation of suppressive antiviral therapy for genital herpes should occur, especially in those in whom there is also adequate inhibition of HIV replication and rising CD4 cell counts. In some PWHIV with less frequent outbreaks of genital herpes, episodic treatment may be substituted. In others, where the pre-treatment pattern of recurrences resumes, suppressive treatment may need to restart (Evidence level IV, Grade C recommendation).

Drug Resistant Genital Herpes

If lesions persist or recur in a PWHIV receiving herpes antiviral therapy, herpes resistance should be suspected and a viral isolate should be obtained for sensitivity testing (Hill, Hunter, & Ellis, 1991; Safrin, 1992; Gnann et al., 2000) (Evidence level Ib, Grade A recommendation).

Both topical 1% foscarnet cream (Gateley et al., 1990) and 1% cidofovir gel (Lalezari et al., 1997) have been shown to produce significant benefits in lesion healing, pain reduction, and virological effect in drug resistant herpes in PWHIV (Evidence level Ib, Grade A recommendation).

There is limited evidence to support the use of topical trifluorothymidine alone or in combination with interferon-alpha (Birch et al., 1992; Kessler et al., 1996) (Evidence level IIb, Grade B recommendation).

Systemic therapy with either foscarnet or cidofovir is generally preferred to treat drug resistant herpes in those with HIV. There is evidence for:

- Foscarnet 40 mg/kg IV daily (Kessler et al., 1996; Safrin et al., 1991; Bestman-Smith & Boivin, 2002) (Evidence level Ib, Grade A recommendation)
- Cidofovir 5 mg/kg body weight weekly IV infusion for 2 weeks (LoPresti et al., 1998; Snoek, 2000; Morfin & Thouvenot, 2003) (Evidence level IV)

Management of Genital Human Papilloma Virus (HPV) Infection in People with HIV

HIV infected women should undergo annual cervical cytology (Evidence level IV, Grade C recommendation).

Treatment of low grade cervical intraepithelial neoplasia (CIN) should be considered, particularly in women with low CD4 cell counts, in view of the risk of disease progression (Evidence level IV, Grade C recommendation).

After full explanation, proctoscopy should be performed in people with HIV who are found to have ano-genital warts and any atypical lesions should be biopsied and sent for histological examination. The role of anal cytology as a screening method is not yet known (Evidence level IV, Grade C recommendation).

Imiquimod 5% cream can be used as a topical treatment for genital warts and may prove more effective than other treatments; however comparative studies have not yet been performed. Surgical methods of wart removal (e.g., diathermy, scissor excision, laser ablation) may be effectively used at an earlier stage of disease management compared to immunocompetent patients (Evidence level IV, Grade C recommendation).

<u>Definitions</u>

Levels of Evidence:

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• Evidence obtained from meta-analysis of randomised controlled trials

Ιb

Evidence obtained from at least one randomised controlled trial

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- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities
- Indicates absence of directly applicable studies of good quality

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS.

The type of supporting evidence is graded and identified for select recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved screening and management of syphilis, genital herpes, and human papilloma virus (HPV) in HIV-positive individuals
- Decreased rates of syphilis and other sexually transmitted infections
- Improved accuracy of diagnostic testing for syphilis in HIV-positive individuals

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This clinical guideline seeks to clarify and add to recommendations in existing Clinical Effectiveness Group (CEG) guidelines relevant to people with human immunodeficiency virus (HIV), rather than repeat these at length.
- Evidence on how best to address the sexual health of those with HIV has only recently begun to emerge, and there are few large randomised studies. Therefore some recommendations given here stem from expert opinion, consensus, and current practice (evidence level IV; see "Rating Scheme for the Strength of the Evidence" field), which may be modified over time as new data emerges. It is hoped that the extensive consultation process in producing this guideline with specific input from HIV community organisations and PWHIV has increased the value of the expert and consensus views.
- There is a notable lack of evidence about how to address the diversity that exists between people with HIV (PWHIV), particularly in a culturally sensitive and appropriate manner or how to take account of differing degrees of immunosuppression. Much of the relevant evidence on the management of sexually transmitted infections (STIs) was produced in the era prior to effective antiretroviral therapy and therefore assumes subsequent loss of immune function, which may no longer invariably be the case.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

Quick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Nandwani R. 2006 United Kingdom national guideline on the sexual health of people with HIV: sexually transmitted infections. London (UK): British Association for Sexual Health and HIV; 2006 Apr. 29 p. [108 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Feb (revised 2006 Apr)

GUIDELINE DEVELOPER(S)

British Association of Sexual Health and HIV - Medical Specialty Society

SOURCE(S) OF FUNDING

No specific or external funding was sought or provided in the development of this guideline.

GUI DELI NE COMMITTEE

Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Lead Author: Dr Rak Nandwani, Consultant Physician, The Sandyford Initiative, Glasgow and The Brownlee Centre, Gartnavel General Hospital, Glasgow

Clinical Effectiveness Group (CEG) Members: Dr Keith Radcliffe (Chair); Dr Jan Welch; Dr Imtyaz Ahmed-Yusuf; Dr Mark FitzGerald; Dr Guy Rooney (Royal College of Physicians Joint Specialty Committee representative); Dr David Daniels (Chair BASHH National Audit Group); Dr Neil Lazaro (Royal College of General Practitioners)

Membership of the BASHH HIV special interest group (at time of drafting): Dr Anton Pozniak (Chair); Dr Rak Nandwani; Dr Adrian Palfreeman; Dr Martin Fisher; Dr Keith Radcliffe; Dr Ian Williams

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declarations of Interest

Dr Nandwani: 3M Healthcare, Boehringer Ingelheim, Gilead and Roche Pharmaceuticals. Nonpharmaceutical: Member of the Broadcasting Council for Scotland (non-remunerated public body).

The Herpes Simplex Advisory Panel, the Human Papilloma Virus and the HIV Special Interest Groups are special interest groups of BASHH. They have received sponsorship by educational grants from several pharmaceutical companies. Members have undertaken research and been funded to attend meetings by these companies. Further details are available from BASHH (www.bashh.org).

ENDORSER(S)

Medical Foundation for AIDS and Sexual Health (UK) - Private Nonprofit Organization

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Medical Society for the Study of Venereal Diseases (MSSVD). Clinical standards for the screening and management of acquired syphilis in HIV-positive adults. London (UK): Medical Society for the Study of Venereal Diseases (MSSVD); 2002 Feb 21. 9 p.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>British</u> Association of Sexual Health and HIV Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 Summary of 2006 United Kingdom National Guideline on the Sexual Health of People with HIV: Sexually Transmitted Infections. London (UK): British Association for Sexual Health and HIV; 2006 Apr. 2 p.

Electronic copies: Available in Portable Document Format (PDF) from the <u>British Association of Sexual Health and HIV Web site</u>.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 8, 2003. The information was verified by the guideline developer on January 24, 2003. This NGC summary was updated by ECRI on July 19, 2006. The updated information was verified by the guideline developer on August 10, 2006.

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